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An Unsealed Package: The Ninth Circuit Creates a Circuit Split When Interpreting FDA Regulations on Food Label Nutrient Content Claims in *Reid v. Johnson & Johnson*

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AN UNSEALED PACKAGE: THE NINTH CIRCUIT CREATES A CIRCUIT SPLIT WHEN INTERPRETING FDA REGULATIONS ON FOOD LABEL NUTRIENT CONTENT CLAIMS IN *REID v. JOHNSON & JOHNSON*

Abstract: On March 13, 2015, in *Reid v. Johnson & Johnson*, the U.S. Court of Appeals for the Ninth Circuit held that the statement "No Trans Fat" on the label of Benecol, a food that contains between 0 and 0.5 grams of trans fat, was not a permitted nutrient content claim. The court held that such a statement made on the label was false or misleading and was therefore not authorized by Food and Drug Administration ("FDA") regulations. The court came to this conclusion despite the Third Circuit reaching the opposite conclusion in 2013, in *Young v. Johnson & Johnson*, regarding the same statement on the same product. Although FDA regulations do not expressly discuss the permissibility of a "No Trans Fat" nutrient content claim, the FDA issued two warning letters stating that this nutrient content claim is unauthorized. This Comment argues that the conflict between the Third and Ninth Circuits demonstrates the need for the FDA to revisit regulations pertaining to trans fat nutrient content claims.

INTRODUCTION

Targeting high levels of sales, eager food manufacturing companies strive to find creative ways to make their products appeal to a large variety of consumers.[1] In the past few decades, the American population has become more health conscious, and food manufacturers have responded by advertising their products as "healthy."[2] At the same time, the Food and Drug Administration ("FDA") has been given more authority to regulate what food manufacturers may claim on the labels of their products.[3]

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[1] *See* Elizabeth O'Connor Tomlinson, *Litigation Concerning Unsubstantiated Health Claims Regarding Food and Beverages*, 127 AM. JURIS. TRIALS 487, § 1, Westlaw (database updated Feb. 2016) (stating that some companies in the food industry have responded to consumers' interest in healthier foods by making statements on the labels of food that are "misleading and unsubstantiated").

[2] *See* Diana R.H. Winters, *The Magical Thinking of Food Labeling: The NLEA as a Failed Statute*, 89 TUL. L. REV. 815, 816 (2015) (stating that in 1990 consumers were learning more about how diet affects health); *see also* Carmen Filosa, *Trans Fat Bans the Next Regulatory Taking?*, 29 J. LEGAL MED. 99, 102 (2008) (noting that Frito-Lay eliminated trans fat from some products so that it would not have to label these products as containing trans fats).

[3] *See* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.). The Nutrition Labeling and Education Act of 1990 ("NLEA") gave the Food and Drug Administration ("FDA") the authority to create regulations on nutrient content claims and to require the Nutrition Facts panel. *See id.*

In March 2015, in *Reid v. Johnson & Johnson* ("*Reid II*"), the U.S. Court of Appeals for the Ninth Circuit considered whether a consumer had a cause of action against the manufacturers of Benecol for including an allegedly misleading statement on its label.[4] Benecol is a margarine-like spread made from partially hydrogenated vegetable oil.[5] Benecol's label contained the statement "No Trans Fat," although Benecol contained between 0 and 0.5 grams of trans fat per serving.[6]

The Ninth Circuit in *Reid II* faced the issue of whether the plaintiff-consumer's claims were preempted by the FDA's Nutrition Labeling and Education Act ("NLEA").[7] Consumers are barred from challenging the validity of a nutrient content claim on the label of a product if the nutrient content claim is authorized by the FDA.[8] Consequently, the court examined whether the FDA had permitted the statement "No Trans Fat" for products that contain less than 0.5 grams of trans fat per serving.[9] Reversing the lower court's ruling, the Ninth Circuit held that the FDA did not authorize such a statement in this context.[10] It concluded that the plaintiff-consumer was not preempted from bringing his claims.[11] In 2013, the Third Circuit reached the opposite conclusion when presented with the same issue for the same product in *Young v. Johnson & Johnson* ("*Young II*").[12]

This Comment argues that the outcome in the Ninth Circuit's *Reid II*, juxtaposed against the outcome in the Third Circuit's *Young II*, demonstrates the need for the FDA to revisit its regulations regarding trans fat nutrient content

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[4] *See* Reid v. Johnson & Johnson (*Reid II*), 780 F.3d 952, 955 (9th Cir. 2015). Reid brought four causes of action: two causes of action under the California Unfair Competition Law, one cause of action under the California False Advertising Law, and one cause of action under the Consumer Legal Remedies Act. *See* Reid v. Johnson & Johnson (*Reid I*), No. 3:11-cv-01310, 2012 WL 4108114, at *2 (S.D. Cal. Sept. 18, 2012), *aff'd in part*, *rev'd in part*, 780 F.3d 952.

[5] *See Reid II*, 780 F.3d at 955.

[6] *See id*. at 957. Reid also contested the labeling of the statement "No Trans Fatty Acids" on Benecol's label. *See Reid I*, 2012 WL 4108114, at *1. Apart from trans fat claims, Reid challenged the inclusion of a statement on Benecol's label regarding the health benefits of plant stanol esters, an ingredient in Benecol, and the statement "Proven to Reduce Cholesterol." *See Reid II*, 780 F.3d at 957.

[7] *See Reid II*, 780 F.3d at 952.

[8] *See* 21 U.S.C. § 343-1(a) (2012) (stating that a plaintiff cannot challenge any statements on the label of food under state law if state law imposes food labeling requirements that conflict with federal requirements).

[9] *See Reid II*, 780 F.3d at 959, 962–63; *see infra* notes 69–80 and accompanying text (examining the Ninth Circuit's analysis in *Reid II*).

[10] *See Reid II*, 780 F.3d at 963.

[11] *See id*.

[12] *See* Young v. Johnson & Johnson (*Young II*), 525 F. App'x 179, 183 (3d Cir. 2013). In 2013, the U.S. Court of Appeals for the Third Circuit, in *Young v. Johnson & Johnson* ("*Young II*"), held that the nutrient content claim "No Trans Fat" was permitted, even though Benecol contained between 0 and 0.5 grams of trans fat per serving. *See id.*

claims.[13] Part I of this Comment discusses the relevant regulations relating to food labeling as well as the factual and procedural history of *Reid II* and *Young II*.[14] Part II explores the circuit split between the Third Circuit and the Ninth Circuit.[15] Finally, Part III argues that the FDA needs to revisit its regulations pertaining to the permissibility of trans fat nutrient content claims in order to achieve uniform labeling requirements and to avoid misleading consumers.[16]

I. Regulations on Food Labeling and Other Courts' Interpretations of Trans Fat Regulations

In the 1980s, as consumers began to understand that nutrition relates to health, food manufacturers increased their usage of unsupported health claims on food labels.[17] In response, Congress sought to improve food-labeling regulations with the passage of the NLEA in 1990.[18] Section A of this Part describes the current state of food-labeling regulations.[19] Section B discusses relevant applications of federal food-labeling regulations and reviews the facts and procedural posture of *Reid II* and *Young II*.[20]

A. Restrictions on Nutrient Content Claims on the Packaging of Food

More than seventy years before *Reid* and *Young*, Congress passed the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA") in order to govern the labeling of food.[21] In 1990, Congress gave the FDA more authority to enforce food-labeling standards by enacting the NLEA, which amended the FDCA.[22] The NLEA provided the FDA with the authority to introduce regula-

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[13] *See infra* notes 81–97 and accompanying text.

[14] *See infra* notes 17–59 and accompanying text.

[15] *See infra* notes 61–80 and accompanying text.

[16] *See infra* notes 81–97 and accompanying text.

[17] *See* Winters, *supra* note 2, at 824–25 (stating that Congress passed the NLEA as a response to the increase of consumers who valued nutrition and concerns over food manufacturers' ability to state unsubstantiated health claims). Food manufacturers were able to make such heath claims because consumers did not have a developed understanding of nutrition. *See id*.

[18] *See* H.R. Rep. No. 101-538, at 8 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3339 (describing the need for legislation that would allow the FDA to enforce accurate labeling of health claims).

[19] *See infra* notes 21–38 and accompanying text.

[20] *See infra* notes 39–59 and accompanying text.

[21] *See* 21 U.S.C. §§ 341–350*l*-1 (containing the provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA") related to food); *see also* Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. Rev. 733, 759 (2003) (providing a brief overview of the statutory support for the FDA's regulations on food labeling).

[22] *See* 104 Stat. at 2353 (stating that the purpose of the NLEA was "to prescribe nutrition labeling for foods, and for other purposes"). Congress passed the NLEA with the goal of establishing national uniform standards in food labeling. *See* H.R. Rep. No. 101-538, at 7 (noting that Congress desired to establish national standards through which "food products disclose the amount of specified nutrients in foods. . . . [and] [e]very covered food would have a uniform nutrition label disclosing the amount of calories, fat, salt and other nutrients").

tions on nutrient content claims and to require the Nutrition Facts panel on food labels.[23]

A nutrient content claim is a statement on a food label that "expressly or implicitly characterizes" the amount of a nutrient that is required to be disclosed separately in the Nutrition Facts panel.[24] As a result of the NLEA, expressed and implied nutrient content claims are permitted only if they are defined in FDA regulations.[25] The "General Principles" regulations permit an expressed nutrient content claim if it is not "false or misleading in any respect."[26] The "Specific Requirements for Nutrient Content Claims" regulations define total fat content claims: statements of "fat free," "free of fat," "no fat," and "zero fat" are permitted if the food contains less than 0.5 grams of total fat per serving.[27] The regulations also contain an equivalent definition for saturated fat.[28] The FDA has not defined a similar claim for trans fat due to unreliable studies on the health consequences of trans fat.[29]

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[23] *See* 21 U.S.C. § 343 (giving the FDA the authority to create more regulations); H.R. REP. NO. 101-538, at 7 (stating the purpose of the NLEA). The NLEA also created regulations on health claims. *See* § 3, 104 Stat. at 2357. Health claims are claims that link the product or one of its ingredients to "a disease or health-related condition." *See* 21 C.F.R. § 101.14(a) (2015).

[24] *See* 21 C.F.R. § 101.13(b). Nutrient content claims are categorized as expressed or implied claims. *See id*. An expressed nutrient content claim explicitly states the amount of a nutrient in the food, such as the statement "contains 5 grams of sugar." *See id.* § 101.13(b)(1). An implied nutrient content claim either implies that a certain level of a nutrient exists in the food or explicitly states the amount of a nutrient in conjunction with a statement relating to health benefits. *See id.* § 101.13(b)(2).

[25] *See id.* § 101.13(b) (stating that nutrient content claims may only be made if they meet the "applicable regulations" of Title 21, chapter I). Nutrient content claims are permitted only if they meet the "General Principles" requirements listed in 21 C.F.R. § 101.13, titled "Nutrient Content Claims-General Principles" and any applicable regulations in Subpart D, titled "Specific Requirements for Nutrient Content Claims." *See id.* §§ 101.13, 101.54–.69.

[26] *See id.* § 101.13(i)(3). In contrast, the regulations permit an implied nutrient content claim about the level of a nutrient if it either includes a disclaimer or is consistent with Subpart D of 21 C.F.R. § 101, titled "Specific Requirements for Nutrient Content Claims." *See id.* § 101.13(i)(1)–(2). For example, "less than 3g of fat per serving" indicates that this level of fat is healthy, but the statement is also consistent with the definition for total fat nutrient content claims listed in Subpart D. *See id.* § 101.13(i)(1). Subpart D's "Specific Requirements for Nutrient Content Claims" regulations contain specific requirements for nutrient content claims on fats. *See id.* § 101.62(b)–(c).

[27] *See id.* § 101.62(b)(1) (stating specific requirements for nutrient content claims regarding total fat). In addition to containing less than 0.5 grams of total fat per serving, total fat content claims must meet other conditions listed in this regulation. *Id.* § 101.62(b) (stating that terms like "no fat" may be used if "the food contains less than 0.5 gram[s] (g) of fat per reference amount customarily consumed and per labeled serving" and if other conditions are met). The "Specific Requirements for Nutrient Content Claims" regulations, which comprise Subpart D, contain specific requirements for nutrient content claims regarding "high," "more," "good source," and "high potency"; "light" or "lite"; the calorie content of foods; the sodium content of foods; fat, fatty acid, and cholesterol content of foods; butter content; and for implied nutrient content claims. *See id.* §§ 101.54–.69; *see also* Winters, *supra* note 2, at 828 (describing regulations for nutrient content claims).

[28] *See* 21 C.F.R. § 101.62(c)(1) (stating specific requirements for nutrient content claims regarding saturated fat).

[29] *See* Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41,434, 41,465 (July 11, 2003) (codified at 21 C.F.R. pt. 101). Although

The Nutrition Facts panel is a required label on the packaging of food and contains nutrition information per serving.[30] Any information within the Nutrition Facts panel is not classified as a nutrient content claim and is therefore not subject to the nutrient content claim requirements.[31] Regulations require that fat contents be disclosed within the Nutrition Facts panel.[32] For example, the amount of total fat, saturated fat, and trans fat must be written as grams per serving and, if the serving contains less than five grams, rounded to the nearest half-gram increment.[33] If the serving contains less than 0.5 grams of total fat, saturated fat, or trans fat, the amount must be written as 0g.[34] Because different regulations apply to statements within the Nutrition Facts panel and to nutrient content claims, a statement authorized within the Nutrition Facts panel may or may not be authorized as a nutrient content claim.[35]

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the FDA required grams of trans fat to be included in the Nutrition Facts panel, it chose to not define trans fat nutrient content claims until more research became available on the appropriate daily consumption value of trans fat. *Id.* at 41464–65; *see also* Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 79 Fed. Reg. 11,880, 11,897 (proposed Mar. 3, 2014) (to be codified at 21 C.F.R. pt. 101) (stating that, as of 2014, scientific information is still not available for the FDA to determine a daily reference value for trans fat); *Reid II*, 780 F.3d at 960 (discussing authorized fat-related nutrient content claims and noting that the FDA did not define a trans fat nutrient content claim). As of the date of publication of this Comment, a daily value for trans fat has not yet been defined. *See* 21 C.F.R. § 101.9(c)(9). The FDA does, however, recognize the negative health consequences of trans fat. *See* Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 79 Fed. Reg. at 11,893 (noting that experts recommend replacing saturated fat and trans fat with healthier fats); Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information, 78 Fed. Reg. 67,169, 67,169 (Nov. 8, 2013) (stating that the FDA "tentatively determined" that partially hydrogenated oils, a large source of artificial trans fat, are not safe for consumption).

[30] *See* 21 C.F.R. § 101.9(b) (requiring nutrients within the Nutrition Facts panel to be measured per serving); *id.* § 101.9(c) (stating what information the Nutrition Facts panel must contain). FDA regulations refer to the Nutrition Facts panel as nutrition labeling. *See id.* § 101.9; *see also* Winters, *supra* note 2, at 816 (stating that the NLEA's objective of disclosing nutrition in the Nutrition Facts panel has been accomplished).

[31] *See* 21 C.F.R. § 101.13(c); *see also* Chacanaca v. Quaker Oats Co., 752 F. Supp. 2d 1111, 1114 (N.D. Cal. 2010) (noting that the statement "0 grams trans fat" within the Nutrition Facts panel of the Chewy Bar box is not a nutrient content claim but that the same information stated outside of the Nutrition Facts panel is a nutrient content claim).

[32] *See* 21 C.F.R. § 101.9(c)(2).

[33] *See id.* § 101.9(c)(2)(ii); *see, e.g.*, *Reid II*, 780 F.3d at 959 (applying regulations for disclosure of trans fat in the Nutrition Facts panel to the food product Benecol); Carrea v. Dreyer's Grand Ice Cream, Inc., 475 F. App'x 113, 115 (9th Cir. 2012) (applying regulations for disclosure of trans fat in the Nutrition Facts panel to the food product Drumstick); *Chacanaca*, 752 F. Supp. 2d at 1119 (applying regulations for disclosure of trans fat in the Nutrition Facts panel to the food product Chewy Bars).

[34] *See* 21 C.F.R. § 101.9(c)(2)(ii).

[35] *See Reid II*, 780 F.3d at 960 (recognizing that the information required in the Nutrition Facts panel is not necessarily permitted outside of the panel).

Litigating food labeling requires determining at the outset whether FDA regulations authorize the claim.[36] The NLEA contains a preemption provision that bars any cause of action that arises from state food-labeling requirements that are not the same as federal requirements.[37] Plaintiffs challenging nutrient content claims under state law causes of action cannot bring their claims if federal regulations permit the challenged statements.[38]

B. Food Labeling Regulations in Practice

Although the NLEA aimed to establish which nutrient claims can be made on the label of a food product, litigation in the area of trans fat reflects the ambiguity that remains in FDA regulations of trans fat.[39] Two recent cases that both addressed the question of trans fat nutrient content claims, *Chacanaca v. Quaker Oats Co.* and *Young v. Johnson & Johnson* ("*Young I*"), utilized different reasoning to come to the determination that the nutrient content claims at issue were authorized by FDA regulations.[40] Similarly, in 2012, in

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[36] *See Chacanaca*, 752 F. Supp. 2d at 1119 (stating that a plaintiff's claim would be preempted if the plaintiff is trying to enforce a requirement that is not the same as FDA regulations). For example, if a plaintiff wants to challenge a nutrient content claim as misleading, he or she can only do so if the nutrient content claim would be misleading under FDA regulations. *See id.*

[37] *See* 21 U.S.C. § 343-1(a)(5). By eliminating state-imposed food labeling requirements that were not identical to federal requirements, Congress pursued its goal of establishing uniform food labeling. *See* H.R. REP. NO. 101-538, at 8. The term "'not identical to' . . . means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food" that "[a]re not imposed by or contained in the applicable provision[s]." 21 C.F.R. § 100.1(c)(4) (2015); *see, e.g.*, CAL. HEALTH & SAFETY CODE § 110100 (West 2012) (stating that all federal food regulations shall be the regulations of California); ILL. ADMIN. CODE tit. 77, § 720.40 (2016) (providing regulations on food labeling); N.Y. COMP. CODES R. & REGS. tit. 1, § 259.1 (2016) (adopting specified federal food labeling regulations for fresh produce as regulations for New York). For example, in 2006, in *Mills v. Giant of Maryland, LLC*, the U.S. District Court for the District of Columbia held that that the state requirement of including a warning on milk products about lactose intolerance exceeded the requirements of the NLEA and was therefore preempted. *See* 441 F. Supp. 2d 104, 108 (D.D.C. 2006).

[38] See *Young II*, 525 F. App'x at 185 (dismissing the plaintiff's complaint because his causes of action were preempted by the NLEA).

[39] *See, e.g.*, Walker v. B&G Foods, Inc., No. 3:15-cv-03772, 2016 WL 463253, at *1 (N.D. Cal. Feb. 8, 2016) (analyzing whether the FDA authorized the claim "0g Trans Fat"); Guttmann v. Nissin Foods (U.S.A.) Co., Inc., No. 3:15-cv-00567, 2015 WL 4309427, at *1 (N.D. Cal. July 15, 2015) (same); Peviani v. Hostess Brands, Inc., 750 F. Supp. 2d 1111, 1114 (C.D. Cal. 2010) (analyzing whether the FDA authorized the claim "0 Grams of Trans Fat"); Red v. Kroger Co., No. 2:10-cv-01025, 2010 WL 4262037, at *5 (C.D. Cal. Sept. 2, 2010) (analyzing whether the FDA authorized the claim "0g Trans Fat"). *Compare Reid II*, 780 F.3d at 963 (finding that including the statement "No Trans Fat" outside the Nutrition Facts label was misleading and thus not permitted), *with Carrea*, 475 F. App'x at 115 (ruling that the nutrient content claim "0g Trans Fat" was not misleading), *and Young II*, 525 F. App'x at 183 (holding that the nutrient content claim "No Trans Fat" was authorized).

[40] *See Young v. Johnson & Johnson* (*Young I*), No. 11-cv-4580, 2012 WL 1372286, at *3 (D. N.J. Feb. 27, 2013) (holding that the statement "No Trans Fat" was a permitted nutrient content claim), *rev'd*, 525 F. App'x 179; *Chacanaca*, 752 F. Supp. 2d at 1121 (holding that the statement "0 grams trans fat" was a permitted nutrient content claim).

Reid v. Johnson & Johnson ("*Reid I*"), the U.S. District Court for the Southern District of California held that the trans fat nutrient content claim at issue was permitted.[41]

In 2010, in *Chacanaca v. Quaker Oats Co.*, the U.S. District Court for the Northern District of California held that the nutrient content claim "0 grams trans fat" on the Chewy Bar label was permitted.[42] Chewy Bars contain between 0 and 0.5 grams of trans fat per serving, and thus, in the Nutrition Facts panel, the amount of trans fat must be rounded down to zero.[43] The court held that the trans fat nutrient content claim was permitted based on supplementary information provided by the FDA in its final rule about food labeling and nutrient content claims.[44] When discussing reference claims, the FDA stated in this supplementary information that rounded and unrounded amounts of a nutrient are nutritionally the same and that relative claims should state information consistently throughout the label.[45] From this, the court concluded that the statement "0 grams trans fat" was not misleading.[46] The statement therefore met the FDA's requirements for an expressed nutrient content claim.[47] As a result, any claims related to the claim "0 grams trans fat" were preempted.[48]

In 2012, in *Young I*, the U.S. District Court for the District of New Jersey determined that the nutrient content claim "No Trans Fat" on the Benecol label was similarly permitted.[49] The plaintiff alleged that the statement was false and misleading because Benecol contains some trans fat.[50] The court reached its

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[41] *See Reid I*, 2012 WL 4108114, at *10–11 (reasoning that the statement "No Trans Fat" was a permitted nutrient content claim).

[42] *See Chacanaca*, 752 F. Supp. 2d at 1121.

[43] *See id.* at 1115–16 (referring to 21 C.F.R. § 101.9(c)(2)(ii) (2010)). The court noted that the "General Principles" regulations do not explicitly address if nutrient content claims should state the actual amount of the nutrient or if they should match the rounded value within the Nutrition Facts panel. *Id.* at 1120.

[44] *See id.* at 1120–21 (quoting 58 Fed. Reg. 44,020, 44,024 (Aug. 18, 1993) (codified at 21 C.F.R. pts. 5 & 101)).

[45] *See id.* (quoting 58 Fed. Reg. at 44,024). Reference claims compare the amount of a nutrient in that product to the amount in another product. *See id*. at 1120.

[46] *See id*. at 1121 (reasoning that if 0 grams of trans fat and an amount between 0 and 0.5 grams of trans fat are nutritionally equivalent, the trans fat nutrient content claim cannot be misleading).

[47] *See id.*

[48] *See id.* If the FDA authorized this statement, by reason of it meeting the requirements of an expressed nutrient content claim, the plaintiff cannot challenge this statement under state law due to the preemption provision. *See* 21 U.S.C. § 343-1(a)(5).

[49] *See Young I*, 2012 WL 1372286, at *5. The court granted the defendant's motion to dismiss. *See id.* at *6.

[50] *See id.* at *5. The plaintiff also alleged that the following statements used on Benecol's label and in its marketing were misleading due to the presence of trans fat: "Proven to Reduce Cholesterol," "No Trans Fatty Acid," "1/2 the fat and calories of margarine," "excellent source of Vitamin E," "Part of a Healthy Lifestyle, " and "heart healthy alternative to butter." *See id.* at *1. Similarly, the plaintiff alleged that a claim indicating that plant stanol provided "health benefits" was misleading. *See id.* The plaintiff brought five causes of action against Johnson & Johnson. *See id*.

conclusion by examining FDA regulations that permit an amount of trans fat that is less than 0.5 grams per serving to be written as 0 in the Nutrition Facts panel.[51] It held that because the statement "No Trans Fat" was authorized in the Nutrition Facts panel, it was similarly permitted outside the panel as a nutrient content claim.[52] On appeal, the Third Circuit affirmed the district court's ruling and held that the claim "No Trans Fat" was permitted by the FDA and that the plaintiff's claims were preempted.[53]

Additionally, in 2012, the district court in *Reid I* held that the nutrient content claim "No Trans Fat" on the Benecol label was an authorized claim.[54] Similar to the plaintiff in *Young*, Reid alleged that the statement "No Trans Fat" was false because Benecol contains small amounts of trans fat.[55] In ruling that the nutrient content claim "No Trans Fat" was permitted, the district court adopted the Ninth Circuit's reasoning from a 2012 unreported decision, *Carrea v. Dreyer's Grand Ice Cream, Inc.*[56] Although the nutrient content claim at issue in *Carrea* was "0g Trans Fat," the district court in *Reid I* found that distinguishing between the statements "0g Trans Fat" and "No Trans Fat" was "unreasonable."[57] On appeal, the Ninth Circuit disagreed with the district court's

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[51] *See id.* at *5 (referencing 21 C.F.R. § 101.9(c)(2)(ii)). The court noted that regulations for the Nutrition Facts panel state that an amount of trans fat that is expressed as zero in the panel is "insignificant." *See id.* (referencing 21 C.F.R. § 101.9(f)).

[52] *See id.*

[53] *See Young II*, 525 F. App'x 179 at 183 (holding that the FDA authorized the claim "No Trans Fat").

[54] *See Reid I*, 2012 WL 4108114, at *10. Reid brought a class action suit against Johnson & Johnson, the manufacturer and seller of Benecol, and McNeil Nutritionals, a wholly owned subsidiary of Johnson & Johnson. *See id.* at *1.

[55] *See id.*; *see also Young II*, 525 F. App'x at 182. Benecol contains between 0 and 0.5 grams of trans fat per serving. *See Reid I*, 2012 WL 4108114, at *1. Reid also alleged that the statement "No Trans Fatty Acids" was false. *See id.*

[56] *See Reid I*, 2012 WL 4108114, at *10 (adopting the reasoning from *Carrea v. Dreyer's Grand Ice Cream, Inc.*, which held that a claim of "0g Trans Fat" was authorized by the FDA, and stating that the "terms are functionally equivalent"). In an unreported 2012 opinion, *Carrea v. Dreyer's Grand Ice Cream, Inc.*, the Ninth Circuit held that the nutrient content claim "0g Trans Fat" was permitted, even though the food product contained between 0 and 0.5 grams of trans fat per serving. *See* 475 F. App'x at 115. The court concluded that the statement was an expressed nutrient content claim that was not "false or misleading" and was thus authorized under the "General Principles" regulations. *See id.* (citing 21 C.F.R. § 101.13(i)(3)). The court held that the supplementary information provided by the FDA for its final rule on food labeling and nutrient content claims, which stated that relative claims should state information consistently throughout the label, did not merely permit but "instruct[ed]" that the trans fat nutrient content claim match information contained within the Nutrition Facts panel. *See id.* (referring to 58 Fed. Reg. at 44,024–25). FDA regulations require that less than 0.5 grams of trans fat per serving be listed in the Nutrition Facts panel as zero grams. *See* 21 C.F.R. § 101.9(c)(2)(ii)). In 2010, the U.S. District Court for the Northern District of California referred to the same language in the same agency final rule, when it stated in *Chacanaca v. Quaker Oats Co.* that the FDA "prefer[red]" consistency between nutrient content claims and information in the Nutrition Facts panel. *See* 752 F. Supp. 2d at 1121 (referring to 58 Fed. Reg. at 44,024).

[57] *See Reid I*, 2012 WL 4108114, at *10 (comparing the nutrient content claim in *Carrea* to that in *Reid*). When discussing standing, the court concluded that because the ingredient list contained

conclusion and held that the trans fat claim at issue was not authorized by the FDA and that Reid's claims were not preempted.[58] This holding contrasted with the Third Circuit's holding in *Young II* and created a circuit split on the issue of trans fat content claims.[59]

II. The Third and Ninth Circuits' Split in Interpreting FDA Regulations on Trans Fat

The U.S. Courts of Appeals for the Third and Ninth Circuits reached opposite decisions when determining if the same nutrient content claim on the same product was authorized by the FDA.[60] In 2013, in *Young v. Johnson & Johnson* ("*Young II*"), the U.S. Court of Appeals for the Third Circuit held that the nutrient content claim "No Trans Fat" on the Benecol label was an authorized claim.[61] Because Benecol contains between 0 and 0.5 grams of trans fat per serving, the amount of trans fat must be rounded down to 0 in the Nutrition Facts panel.[62] The court concluded that, based on the Nutrition Facts panel requirements, the nutrient content claims were authorized on a per-serving basis.[63] First, the court noted that FDA regulations consider less than 0.5 grams of trans fat to be "an insignificant amount" in the per-serving context.[64] Next, the court considered that the claims "no fat" and "no saturated fat" were authorized claims based on the grams the product contains per serving, even though the claims make no mention of serving size.[65] Finally, the court referred to the supplementary information for the final rule on food labeling and

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partially hydrogenated oils, a reasonable consumer would not assume that the statement "mean[s] that Benecol products do not contain any trans fat." *See id.* at *4.

[58] *See Reid II*, 780 F.3d at 963 (holding that the plaintiff's claims relating to the trans fat statements were not preempted by the NLEA).

[59] *See id.* (holding that the "No Trans Fat" content claim was not authorized by FDA regulations); *Young II*, 525 F. App'x at 183 (holding that the "No Trans Fat" content claim was permitted by FDA regulations).

[60] *See* Reid v. Johnson & Johnson (*Reid II*), 780 F.3d 952, 963 (9th Cir. 2015) (holding that the statement "No Trans Fat" on Benecol was not authorized); Young v. Johnson & Johnson (*Young II*), 525 F. App'x 179, 183 (3d Cir. 2013) (holding that the statement "No Trans Fat" on Benecol was authorized).

[61] *See Young II*, 525 F. App'x at 183. The court also held that the statement "No Trans Fatty Acids," also on the label of Benecol, was a permitted nutrient content claim. *See id.* at 180, 183.

[62] *See id.* at 182. The plaintiff argued that the statement "No Trans Fat" was misleading for the product as a whole, not on a per-serving basis. *See id.*

[63] *See id.* (reasoning that nutrient content claims should match nutrient information based on the per-serving amount provided in the Nutrition Facts panel). The plaintiff in *Young* argued that the trans fat nutrient content claims were false and misleading because such statements were not expressly authorized for the product as a whole. *See id*. Young compared the trans fat nutrient content claims to the trans fat per serving statements that are expressly authorized in the Nutrition Facts panel. *See id.*

[64] *See id.* (stating that 21 C.F.R. § 101.9(f)(1) (2013) explicitly states that 0.5 grams of trans fat per serving is insignificant).

[65] *See id.* at 182–83 (referring to 21 C.F.R. § 101.62(b)–(c) (2013)).

nutrient content claims, which stated that in order to prevent consumer confusion, a food product shall be considered "free" of a nutrient based on the amount of that nutrient per serving.[66] Because the court concluded that the regulations authorize nutrient content claims based on the level of that nutrient in each serving, the court held that the claim "No Trans Fat" was not misleading and therefore was authorized by FDA regulations.[67] In its opinion, the Third Circuit cited the Southern District of California's 2012 decision *Reid v. Johnson & Johnson* ("*Reid I*") and the Ninth Circuit's 2012 unreported decision in *Carrea v. Dreyer's Grand Ice Cream, Inc.* as support for its holding.[68]

In 2015, in *Reid v. Johnson & Johnson* ("*Reid II*"), the U.S. Court of Appeals for the Ninth Circuit reversed the district court's finding that the plaintiff's claims regarding false labeling of "No Trans Fat" were preempted.[69] In holding that the statement "No Trans Fat" was not authorized by FDA regulations, the Ninth Circuit's holding was opposite to the Third Circuit's in *Young II*, creating a circuit split.[70] The Ninth Circuit in *Reid II* held that the statement "No Trans Fat" was not a permitted expressed nutrient content claim under the nutrition labeling "General Principles" regulations.[71] The statement "No Trans Fat" is an expressed nutrient content claim because it directly states the amount of trans fat in Benecol.[72] The "General Principles" regulations only permit expressed nutrient content claims that are not "false or misleading."[73]

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[66] *See id.* at 183 (citing 58 Fed. Reg. 44,020, 44,025 (Aug. 18, 1993) (codified at 21 C.F.R. pts. 5 & 101)). The court recognized that nutrient content claims based on per-serving size might not necessarily be accurate on a per product basis. *See id.*

[67] *See id.* Therefore, the plaintiff's claims related to the statement "No Trans Fat" were preempted. *See id.*

[68] *See id.* at 183 n.5 (citing the *Carrea v. Dreyer's Grand Ice Cream*, *Inc.*, *Reid v. Johnson & Johnson* ("*Reid I*"), and *Chacanaca v. Quaker Oats Co.* decisions as support).

[69] *See Reid II*, 780 F.3d at 963.

[70] *Compare id.* (finding that including the statement "No Trans Fat" outside the Nutrition Facts label was misleading and not preempted), *with Young II*, 525 F. App'x at 183 (ruling that including the statement "No Trans Fat" outside the Nutrition Facts Label was consistent with FDA regulations). The *Reid II* decision also conflicted with the Ninth Circuit's unreported decision in *Carrea v. Dreyer's Grand Ice Cream*, *Inc. Compare Reid II*, 780 F.3d at 963 (finding that including the statement "No Trans Fat" outside the Nutrition Facts label was misleading), *with* Carrea v. Dreyer's Grand Ice Cream, Inc., 475 F. App'x 113, 115 (9th Cir. 2012) (dismissing plaintiff's allegations that statements outside of the Nutrition Facts label that Drumsticks have "0g Trans Fat" were misleading).

[71] *See Reid II*, 780 F.3d at 962 (referencing 21 C.F.R. § 101.13(i) (2014)). The court reasoned that if the statement "No Trans Fats" is false or misleading, then it is not an authorized expressed nutrient content claim. *See id.*

[72] *See id.* (referencing 21 C.F.R. § 101.13(b)(1)–(2)).

[73] *See id.* (referencing 21 C.F.R. § 101.13(i)(3)). FDA regulations permit express nutrient content claims if they are "not false or misleading in any respect." 21 C.F.R. § 101.13(i)(3) (2015).

The court held that the statement "No Trans Fat" on Benecol's label was misleading and therefore was not permitted.[74]

The Ninth Circuit determined that Benecol's trans fat nutrient content claim was misleading by examining FDA warning letters and by analyzing the purpose of the FDA's "Specific Requirements for Nutrient Content Claims" regulations for total fat and saturated fat.[75] In two FDA warning letters, the FDA indicated that the statement "No Trans Fat" was an unauthorized nutrient content claim.[76] The court determined that the FDA explicitly authorized "No Fat" and "No Saturated Fat" as nutrient content claims when the product contains less than 0.5 grams because such claims are authorized under the "Specific Requirements for Nutrient Content Claims" regulations, even though those claims are not authorized under the "General Principles" regulations.[77] The FDA chose not to authorize a trans fat nutrient content claim because of insufficient scientific information on the appropriate daily consumption value of trans fat.[78] Thus, the court concluded that "No Fat" and "No Saturated Fat" claims were not authorized under the "General Principles" regulations because they were misleading.[79] Accordingly, if "No Fat" and "No Saturated Fat" were misleading when the product contained small amounts of that nutrient per serving, the court concluded that "No Trans Fat" was also misleading when the product contained a small amount of that nutrient per serving.[80]

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[74] *See Reid II*, 780 F.3d at 962 (reasoning that the statement "No Trans Fat" on the product's label misleads the consumer to think there is none of that nutrient when in actuality there is between 0 and 0.5 grams of trans fat per serving).

[75] *See id.* at 962–93. The FDA issues warning letters as a means of informal enforcement action. 21 C.F.R. § 100.2 (2015). Warning letters are a common type of enforcement measure. *See* 1 WAYNE L. PINES, FDA ADVERTISING AND PROMOTION MANUAL ¶ 910 (2015), 2004 WL 5032786. "Specific Requirements for Nutrient Content Claims" for total fat and saturated fat is contained in 21 C.F.R. § 101.62. *See* 21 C.F.R. § 101.62 (2015).

[76] *See Reid II*, 780 F.3d at 962 (stating that the court will "defer to the FDA's interpretation of its own rules").

[77] *See id.* at 962–63 (referring to 21 C.F.R. §§ 101.13(i)(3) and 101.62(b)–(c)). The court explained that if the statements "No Fat" or "No Saturated Fat" were permitted under the "General Principles" regulations, then the "Specific Requirements for Nutrient Content Claims" regulations for fat and total fat would be superfluous. *See id.* at 963.

[78] *See id.* at 963 (referencing 68 Fed. Reg. 41,434, 41,464–65 (July 11, 2003) (codified at 21 C.F.R. pt. 101), which states that because not enough scientific information exists to support a daily reference value for trans fat, the FDA declined defining a trans fat nutrient content claim).

[79] *See id.* (reasoning that the statement "No Fat" or "No Saturated Fat" is misleading if the product contains small amounts of fat or saturated fat, respectively, per serving).

[80] *See id.* (reasoning that per 21 C.F.R. § 101.13(i)(3), "No Trans Fat," "No Saturated Fat," and "No Fat" should be treated the same when determining if the statements are false or misleading).

III. TRANS FAT NUTRIENT CONTENT CLAIM REGULATIONS ARE A STICKY MESS

In 2015, in *Reid v. Johnson & Johnson* ("*Reid II*"), the U.S. Court of Appeals for the Ninth Circuit reached its conclusion that the FDA had not authorized the trans fat nutrient content claim at issue, despite the U.S. Court of Appeals for the Third Circuit reaching the opposite conclusion for the same product in 2013 in *Young v. Johnson & Johnson* ("*Young II*").[81] Inconsistent judicial interpretation regarding the claims "No Trans Fat" and "0g Trans Fat" on products that have small amounts of trans fat per serving demonstrates the inadequacy of the trans fat regulations that have stemmed from the NLEA.[82] In the area of trans fat nutrient content claims, the FDA is not fulfilling the NLEA's objective of providing uniform food labeling standards, as evidenced by varying outcomes in two cases within different circuits that discuss the same nutrient content claim for the same product.[83] The FDA should revisit its regulations pertaining to trans fat nutrient content claims to provide courts with the means to consistently interpret the permissibility of these claims under the FDA and to avoid misleading consumers.[84]

The U.S. Court of Appeals for the Third Circuit, the U.S. Court of Appeals for the Ninth Circuit, and district courts within the Ninth Circuit have

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[81] *Compare* Reid v. Johnson & Johnson (*Reid II*), 780 F.3d 952, 963 (9th Cir. 2015) (holding that the nutrient content claim "No Trans Fat" was not authorized by the FDA, *with* Young v. Johnson & Johnson (*Young II*), 525 F. App'x 179, 183 (3d Cir. 2013) (holding that the nutrient content claim "No Trans Fat" was permitted).

[82] *See* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.); Hilary G. Buttrick & Courtney Droms Hatch, *Pomegranate Juice Can Do That? Navigating the Jurisdictional Landscape of Food Health Claim Regulation in a Post*-POM Wonderful *World*, 49 IND. L. REV. 267, 288 (2016) (recognizing that determining whether a plaintiff's claim is preempted by the NLEA can be difficult when FDA regulations are relevant but do not explicitly address the claim); Winters, *supra* note 2, at 815 (arguing for the repeal of the NLEA's nutrient content claim provisions); Sylvia Zarski, Comment, *Can You Judge Your Food by Looking at Its Cover? How Courts' Application of Federal Preemption Allows Misleading Food Labeling to Slip Through the Regulatory Cracks*, 64 DEPAUL L. REV. 1119, 1137 (2015) (stating that the Ninth Circuit in *Carrea v. Dreyer's Grand Ice Cream, Inc.* should not have held the claim "0g trans fat" to be preempted).

[83] *See* Winters, *supra* note 2, at 859 (arguing that the FDA has failed to achieve uniform food labeling standards); *supra* notes 61–80 and accompanying text (discussing two different outcomes regarding the permissibility of trans fat nutrient content claims for the same product). Congress passed the NLEA with the goal of establishing national uniform standards in food labeling. *See* H.R. REP. NO. 101-538, at 7 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3339.

[84] *See* Jennifer L. Pomeranz, *A Comprehensive Strategy to Overhaul FDA Authority for Misleading Food Labels*, 39 AM. J.L. & MED. 617, 638–41 (2013) (proposing that the FDA be given the authority to require "preauthorization" for nutrient content claims to reduce the amount of misleading claims); Winters, *supra* note 2, at 861 (arguing for the repeal of the NLEA's nutrient content claim provisions); Zarski, *supra* note 82, at 1137 (arguing that courts have held that consumers' claims are preempted when their claims are based on misleading statements on food labels).

struggled to analyze the permissibility of such claims.[85] The Ninth Circuit, in determining the permissibility of the claims "No Trans Fat" and "0g Trans Fat" looked to the FDA by considering related FDA regulations, supplementary information published with a particular final rule, and warning letters.[86] In an unreported 2012 opinion, *Carrea v. Dreyer's Grand Ice Cream, Inc.*, the Ninth Circuit reasoned that the claim "0g Trans Fat" was permitted based on a particular final rule's supplementary information discussing reference claims.[87]

The courts in *Reid II* and *Young II* interpreted differently whether the claim "No Trans Fat" on the same food product was "false or misleading" under FDA regulations.[88] The Ninth Circuit in *Reid II* came to its conclusion by examining FDA warning letters that specifically stated that the claim "No Trans Fat" was not permitted and by analyzing the purpose of the "Specific Requirements for Nutrient Content Claims" regulations for total fat and saturated fat.[89] In contrast, the Third Circuit in *Young II* reasoned that the claim at issue was permitted by considering related FDA regulations and by considering a particular final rule's supplementary information stating that food products are considered "free" of a nutrient based on the amount of that nutrient per serving.[90]

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[85] *See Reid II*, 780 F.3d at 962–93 (reversing the district court's holding that the plaintiff's claim was preempted by examining different authority than the district court); *Young II*, 525 F. App'x at 182 (holding that the nutrient content claim "No Trans Fat" was permitted, even though the plaintiff argued that FDA regulations do not "expressly permit" such a claim); Guttmann v. Nissin Foods (U.S.A.) Co., Inc., No. 3:15-cv-00567, 2015 WL 4309427, at *3 (N.D. Cal. July 15, 2015) (citing Chacanaca v. Quaker Oats Co., 752 F. Supp. 2d 1111 (N.D. Cal. 2010)) (stating that, in 2010, in *Chacanaca v. Quaker Oats Co.*, the judge applied a principle from the FDA's discussion of relative claims to nutrient content claims); Reid v. Johnson & Johnson (*Reid I*), No. 3:11-cv-01310, 2012 WL 4108114, at *10 (S.D. Cal. Sept. 18, 2012) (relying on the Ninth Circuit's reasoning in *Carrea*), *aff'd in part*, *rev'd in part*, 780 F.3d 952; *see also* Carrea v. Dreyer's Grand Ice Cream, Inc., 475 F. App'x 113, 115 (9th Cir. 2012) (holding that the content claim "0g trans fat" is permitted by FDA regulations); Winters, *supra* note 2, at 850 (stating that the court's reasoning in *Chacanaca* was "intensive, time-consuming, and disputable").

[86] *See Reid II*, 780 F.3d at 962–93 (examining the purpose of other regulations and warning letters); *Carrea*, 475 F. App'x at 115 (considering supplementary information to the final rule in 58 Fed. Reg. 44,020 (Aug. 18, 1993) (codified at 21 C.F.R. pts. 5 & 101)); *see also* Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 414 (1945) (reasoning that the administrative interpretation of a regulation is controlling "unless it is plainly erroneous or inconsistent with the regulation"). FDA warning letters are informal communications that do not necessarily represent the FDA's view. *See generally* Paige S. Goodwin & Kevin T. Jacobs, *A Primer on the Admissibility of FDA Warning Letters*, 80 DEF. COUNS. J. 136 (2013) (discussing the admissibility of FDA warning letters in court).

[87] *See Carrea*, 475 F. App'x at 115 (referring to 58 Fed. Reg. at 44,024).

[88] *Compare Reid II*, 780 F.3d at 962 (holding that the claim "No Trans Fat" was not authorized), *with Young II*, 525 F. App'x at 182 (holding that the claim "No Trans Fat" was authorized).

[89] *See Reid II*, 780 F.3d at 962–93.

[90] *See id.* (referring to FDA warning letters and the purpose of 21 C.F.R. § 101.62 (2014)); *Young II*, 525 F. App'x at 183 (referring to 21 C.F.R. § 101.9(f)(1) (2013), 21 C.F.R. § 101.62(b)–(c) (2013), and 58 Fed. Reg. at 44,025).

To resolve the issue of inconsistent interpretation by courts, the FDA should address differences in the wording of such trans fat claims.[91] Along with interpreting without uniformity if the claims "0g Trans Fat" and "No Trans Fat" are permitted by the FDA, district courts within the Ninth Circuit have disagreed on whether these claims are exact substitutes for each other.[92] The district court in *Reid* held that these claims should be treated the same.[93] Another district court, however, held that the claim "0 grams trans fat" required a different analysis than the claim "No Trans Fat."[94]

The FDA should also regulate trans fat nutrient content claims in a way that consumers will best understand.[95] As reflected in the amount of litigation on trans fat nutrient content claims, consumers do not understand such nutrient content claims' meaning and are being misled.[96] The FDA must conform to its

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[91] *See* 1 JAMES T. O'REILLY & KATHARINE A. VAN TASSEL, FOOD AND DRUG ADMIN. § 10:49, Westlaw (database updated Dec. 2015) (concluding that statements on food labels in which the wording exactly matches statements defined in the regulations are "clearly" permitted nutrient content claims); BRUCE SILVERGLADE & ILENE RINGEL HELLER, CTR. FOR SCI. IN THE PUB. INTEREST, FOOD LABELING CHAOS: THE CASE FOR REFORM (2010), https://www.cspinet.org/new/pdf/food_labeling_chaos_report.pdf [https://perma.cc/U82F-Y6AP] (advocating that the FDA should expand their regulations so that courts no longer have to interpret the current regulations' meanings); *see, e.g.*, 21 C.F.R. § 101.62(b) (2015) (stating what specific terms are permitted for total fat claims); *id.* § 101.62(c) (stating what specific terms are permitted for saturated fat claims); *id.* § 101.62(d) (stating what specific terms are permitted for cholesterol claims).

[92] *Compare Reid I*, 2012 WL 4108114, at *10 (indicating that "0g Trans Fat" and "No Trans Fat" have the same meaning), *with* Walker v. B&G Foods, Inc., No. 3:15-cv-03772, 2016 WL 463253, at *4 (N.D. Cal. Feb. 8, 2016) (suggesting that these statements may not be interchangeable), *and Guttmann*, 2015 WL 4309427, at *3 (stating that these statements require different analyses).

[93] *See Reid I*, 2012 WL 4108114, at *10 (stating that distinguishing between the statements "0g Trans Fat" and "No Trans Fat" was "unreasonable").

[94] *See Walker*, 2016 WL 463253, at *4 (stating that while the FDA has provided guidance on the claim "No Trans Fat," it has not commented on the claim "0g Trans Fat"); *Guttmann*, 2015 WL 4309427, at *3 (stating that *Reid II* does not apply to the preemption analysis of the claim "0g Trans Fat" because the warning letters relied on by *Reid II* did not address the claim "0g Trans Fat" but instead "No Trans Fat).

[95] *See* Winters, *supra* note 2, at 861 (noting that nutrient content claims have failed to provide "transparency and accuracy" to consumers); *see also* Zarski, *supra* note 82, at 1150 (stating that *Carrea* is one example of an instance in which a court has interpreted the FDA's preemption provision too broadly, resulting in preventing consumers from challenging misleading statements). *But see* Zarski, *supra* note 82, at 1150 (noting that some of the information that the FDA allows or necessitates on food labels has the ability to mislead consumers).

[96] *See* Pomeranz, *supra* note 84, at 621–22 (pointing out that consumers are confused by the meaning of nutrient content claims on food labels and stating that "[m]isleading and deceptive claims are expressly permitted or tactically ignored" by the FDA); *see, e.g.*, *Reid II*, 780 F.3d at 962–63 (analyzing whether the statement "No Trans Fat" was misleading); *Young II*, 525 F. App'x at 182–83 (same); *Carrea*, 475 F. App'x at 115 (confirming the lower court's ruling that the claim "0g Trans Fat" was not misleading); *Walker*, 2016 WL 463253, at *3–4 (analyzing whether the claim "0g Trans Fat" was misleading); *Guttmann*, 2015 WL 4309427, at *2–3 (analyzing whether the nutrient content claim "0g Trans Fat" was misleading and therefore not permitted); Peviani v. Hostess Brands, Inc., 750 F. Supp. 2d 1111, 1119–20 (C.D. Cal. 2010) (analyzing whether the FDA authorized the claim "0 Grams of Trans Fat"); Red v. Kroger Co., No. 2:10-cv-01025, 2010 WL 4262037, at *4–5 (C.D. Cal.

mandate under the First Amendment to facilitate accurate speech that is not misleading to consumers.[97]

CONCLUSION

The Ninth Circuit's holding in *Reid II* demonstrates the need for the FDA to provide clear regulations on trans fat nutrient content claims. *Reid* held that the FDA did not authorize the statement "No Trans Fat" based on FDA warning letters stating that this claim was not permissible. In *Young II*, however, the Third Circuit held that the same statement on the same product was authorized by the FDA. In order to ensure uniform application of FDA regulations, the FDA needs to revisit rules on trans fat nutrient content claims. Revising such regulations will assist the FDA in achieving the NLEA's goal of providing uniform food labeling requirements and will help ensure that manufacturers do not mislead consumers.

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Sept. 2, 2010) (analyzing whether the claim "0g Trans Fat" was misleading). For example, the plaintiff in *Reid v. Johnson & Johnson* interpreted "No Trans Fat" to mean that the product did not contain any trans fats throughout the product. *See Reid II*, 780 F.3d at 962. Similarly, the plaintiffs in *Chacanaca* interpreted "0 grams trans fat" to mean the product did not contain any trans fats. *See* 752 F. Supp. 2d at 1119. Likewise, the plaintiff in *Carrea* understood "0g Trans Fat" to mean that the product did not contain any trans fats. *See* 2011 WL 159380, at *1.

[97] *See* U.S. CONST. amend. I; Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41,434, 41,437, 41,465 (July 11, 2003) (codified at 21 C.F.R. pt. 101) (acknowledging, in the supplementary information for the rule requiring the disclosure of trans fats in the Nutrition Facts panel, that the FDA has the responsibility to ensure "truthful and nonmisleading" speech on the labels of food products).